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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,381	04/17/2001	Mikiko Suga	206018US0	5139

22850 7590 02/24/2004

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/835,381	SUGA ET AL.	
	Examiner	Art Unit	
	Christian L Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 2,3,6,7,9,10,12,13,15,16 and 18-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 2,3,6,7,9,10,12,13,15,16 and 18-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 17 April 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 11/26/2003 has been entered.

2. Claims 2, 3, 6, 7, 9, 10, 12, 13, 15, 16, and 18-26 are under consideration in this Office Action.

3. The rejection of claims 2, 3, 6, 7, 9, 10, 12, 13, 15, 16, and 18-23 under 35 USC 101 in the previous Office Action has been withdrawn in view of Applicants' arguments filed on 11/26/2003. New rejections and new grounds for rejection are stated in the instant Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2, 3, 6, 7, 9, 10, 12, 13, 15, 16, and 18-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed 11/26/2003 have been fully considered but they are not persuasive. Applicant's position is that the PCR product of SEQ ID NO: 15 and SEQ ID NO: 16 does not encompass a large diverse number of nucleotide sequences and that PCR methods, conditions, and protocol are standard. The Examiner respectfully disagrees for reasons of record as supplemented below.

At issue is not the PCR methods, conditions, or protocols known in the art but the scope of the claimed invention which is not adequately described by the specification. The claims are genus claims which encompass any argR gene of any nucleotide sequence including yet to be discovered nucleotide sequences which are obtained by PCR using primers of SEQ ID NO: 15

and SEQ ID NO: 16. Furthermore, the claims are directed to any argR gene which comprise yet to be discovered untranslated region(s), promoter(s), and regulatory element(s).

The specification does not provide a written description of any argR of any nucleotide sequence other than the nucleotide of SEQ ID NO: 17. The specification does not provide a written description of yet to be discovered untranslated region(s), promoter(s), and regulatory element(s) of any argR gene. Furthermore, there is no written description for the all the PCR products obtainable from PCR using primers of SEQ ID NO: 15 and SEQ ID NO: 16 which are expected to be vary greatly in structure and nucleotide sequence.

The specification only provides a written description of a single representative species as encompassed by the genus claims, specifically, a *Brevibacterium lactofermentum* strain containing a disrupted argR gene, wherein said disrupted argR gene consists of nucleotides 1851-2395 of SEQ ID NO: 17, which is 600bp shorter than the wild type argR gene of SEQ ID NO: 17 (see Example 3 in specification).

Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

6. Claims 2, 3, 6, 7, 9, 10, 12, 13, 15, 16, and 18-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated coryneform bacterium containing a disrupted argR gene consisting of nucleotides 1851-2395 of SEQ ID NO: 17, and a method for making L-arginine using said coryneform bacteria containing a disrupted argR gene consisting of nucleotides 1851-2395 of SEQ ID NO: 17, does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants' arguments filed 11/26/2003 have been fully considered but they are not persuasive. Applicant's position is that the PCR product of SEQ ID NO: 15 and SEQ ID NO: 16 does not encompass a large diverse number of nucleotide sequences and that PCR methods, conditions, and protocol are standard to one of skill in the art. The Examiner respectfully disagrees for reasons of record as supplemented below.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any coryneform bacterium having any argR of any nucleotide sequence obtained from PCR using primers of SEQ ID NO: 15 and SEQ

ID NO: 16 and a method for making L- arginine using said coryneform bacterium.

The specification provides guidance for an isolated coryneform bacterium containing a disrupted argR gene consisting of nucleotides 1851-2395 of SEQ ID NO: 17 and a method for making L-arginine using said coryneform bacteria containing a disrupted argR gene consisting of nucleotides 1851-2395 of SEQ ID NO: 17 and an example of a *Brevibacterium lactofermentum* (strain AJ13029deltaR) containing a disrupted argR gene, wherein said disrupted argR gene consists of nucleotides 1851-2395 of SEQ ID NO: 17, which is 600bp shorter than the wild type argR gene of SEQ ID NO: 17 and a method for making L-arginine using said coryneform bacteria containing a disrupted argR gene consisting of nucleotides 1851-2395 of SEQ ID NO: 17 (see Example 3 in the specification). Example 3 only shows no other embodiment to the artisan other than how to make an isolated coryneform bacterium containing a disrupted argR gene consisting of nucleotides 1851-2395 of SEQ ID NO: 17 and use said coryneform bacterium for the production of L-arginine.

The specification does not provide guidance for making any argR of any nucleotide sequence, any coryneformbacteria containing any disrupted argR gene of any nucleotide sequence, and a method for making L-arginine using said coryneformbacteria. Limiting the claims to recite that the argR gene is amplified by PCR primers of SEQ ID NO: 15 and 16 does not meet the enablement requirement because any polynucleotide of any nucleotide sequence can be amplified and that undue experimentation must be performed to screen each and every PCR product to determine whether the amplified PCR product encodes an argR gene product. Identifying which PCR product encodes an argR gene product can not be predicted since any PCR product of any nucleotide sequence can be amplified by the primers of SEQ ID NO: 15 and SEQ ID NO: 16. Furthermore, empirical experimentation must be performed to identify yet to be discovered untranslated region(s), promoter(s), and regulatory element(s) of any argR gene. Guidance regarding how to search or screen for the invention is not guidance for making the invention.

The Examiner finds that one skilled in the art would require additional guidance, such as the specific nucleotide sequence of the PCR product which encodes the disrupted argR gene. Without such a guidance, the experimentation left to those skilled in the art is undue.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The

examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

TEKCHAND SAIDHA
PRIMARY EXAMINER

2/23/04